



Wyeth Pharmaceuticals

Excerpt from Report of Clinical Study (Feb. 1, 2001)
Protocol 0600D1-159-EU
Supportive Tables ST9-1 and ST9-2

SUPPORTIVE TABLE ST9-1. NUMBER (%) OF SUBJECTS REPORTING ADVERSE EVENTS

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REPORT 5-5

NUMBER (%) OF SUBJECTS REPORTING ADVERSE EVENTS

BODY SYSTEM (1)	NONE (N = 20)	Venlafaxine 75 mg (Carbopol) (N = 20)	Venlafaxine 75 mg (Long) (N = 20)	Venlafaxine 75 mg (Short) (N = 20)
ADVERSE EVENT				
ANY ADVERSE EVENT	1 (5.0)	10 (50.0)	5 (25.0)	4 (20.0)
BODY AS A WHOLE	1 (5.0)	0	0	0
ACCIDENTAL INJURY	1 (5.0)	0	0	0
DIGESTIVE SYSTEM	0	10 (50.0)	5 (25.0)	4 (20.0)
NAUSEA	0	10 (50.0)	5 (25.0)	4 (20.0)

BODY SYSTEM (1)	Venlafaxine 75 mg (Wax) (N = 20)	Venlafaxine 75 mg (XR-Capsule) (N = 19)
ADVERSE EVENT		
ANY ADVERSE EVENT	4 (20.0)	7 (36.8)
BODY AS A WHOLE	0	0
ACCIDENTAL INJURY	0	0
DIGESTIVE SYSTEM	4 (20.0)	7 (36.8)
NAUSEA	4 (20.0)	7 (36.8)

NOTE (1) - BODY SYSTEM TOTALS ARE NOT NECESSARILY THE SUM OF THE INDIVIDUAL ADVERSE EVENTS SINCE A PATIENT MAY REPORT TWO OR MORE DIFFERENT ADVERSE EVENTS IN THE SAME BODY SYSTEM

SUPPORTIVE TABLE ST9-2. NUMBER (%) OF SUBJECTS REPORTING ADVERSE EVENTS BY SEVERITY AND DRUG RELATIONSHIP INCLUDING IDENTIFICATION OF SUBJECTS

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NUMBER (%) OF SUBJECTS REPORTING ADVERSE EVENTS
BY SEVERITY(1) AND DRUG RELATIONSHIP(2) INCLUDING IDENTIFICATION OF SUBJECTS

TREATMENT: NONE
TOTAL SUBJECTS: 20

BODY SYSTEM (3) ADVERSE EVENT	MILD		MODERATE		SEVERE		TOTAL	
	REL.	NOT REL.	REL.	NOT REL.	REL.	NOT REL.	REL.	NOT REL.
ANY ADVERSE EVENT	0	0	0	0	0	1 (5.0)	0	1 (5.0)
BODY AS A WHOLE	0	0	0	0	0	1 (5.0)	0	1 (5.0)
ACCIDENTAL INJURY	0	0	0	0	0	1 (5.0) 001-000002	0	1 (5.0)

NOTE. (1)- SEVERITY IS REGARDED AS THE MAXIMUM INTENSITY REPORTED FOR THE ADVERSE EVENTS
(2)- DRUG RELATIONSHIP IS REGARDED AS THE MAXIMUM DRUG RELATED EVENT FOR THE EVENT SELECTED BY THE SEVERITY
(3)- BODY SYSTEM TOTALS ARE NOT NECESSARILY THE SUM OF THE INDIVIDUAL ADVERSE EVENTS SINCE A PATIENT MAY REPORT TWO OR MORE DIFFERENT ADVERSE EVENTS IN THE SAME BODY SYSTEM

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NUMBER (1) OF SUBJECTS REPORTING ADVERSE EVENTS
BY SEVERITY(1) AND DRUG RELATIONSHIP(2) INCLUDING IDENTIFICATION OF SUBJECTSTREATMENT: Venlafaxine 75 mg (Carbopol)
TOTAL SUBJECTS: 20

BODY SYSTEM (3) ADVERSE EVENT	MILD		MODERATE		SEVERE		TOTAL	
	REL.	NOT REL.	REL.	NOT REL.	REL.	NOT REL.	REL.	NOT REL.
ANY ADVERSE EVENT	10 (50.0)	0	0	0	0	0	10 (50.0)	0
DIGESTIVE SYSTEM	10 (50.0)	0	0	0	0	0	10 (50.0)	0
NAUSEA	10 (50.0)	0	0	0	0	0	10 (50.0)	0
	001-000001							
	001-000002							
	001-000004							
	001-000006							
	001-000007							
	001-000008							
	001-000009							
	001-000010							
	001-000016							
	001-000018							

NOTE (1)- SEVERITY IS REGARDED AS THE MAXIMUM INTENSITY REPORTED FOR THE ADVERSE EVENTS
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REPORT 5-7

NUMBER (%) OF SUBJECTS REPORTING ADVERSE EVENTS
BY SEVERITY(1) AND DRUG RELATIONSHIP(2) INCLUDING IDENTIFICATION OF SUBJECTS

TREATMENT: Venlafaxine 75 mg (Long)

TOTAL SUBJECTS: 20

BODY SYSTEM (3) ADVERSE EVENT	MILD		MODERATE		SEVERE		TOTAL	
	REL.	NOT REL.	REL.	NOT REL.	REL.	NOT REL.	REL.	NOT REL.
ANY ADVERSE EVENT	4 (20.0)	0	1 (5.0)	0	0	0	5 (25.0)	0
DIGESTIVE SYSTEM	4 (20.0)	0	1 (5.0)	0	0	0	5 (25.0)	0
NAUSEA	4 (20.0)	0	1 (5.0)	0	0	0	5 (25.0)	0
	001-000002		001-000007					
	001-000008							
	001-000010							
	001-000019							

NOTE: (1)- SEVERITY IS REGARDED AS THE MAXIMUM INTENSITY REPORTED FOR THE ADVERSE EVENTS
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(3)- BODY SYSTEM TOTALS ARE NOT NECESSARILY THE SUM OF THE INDIVIDUAL ADVERSE EVENTS SINCE A PATIENT MAY REPORT TWO OR MORE DIFFERENT ADVERSE EVENTS IN THE SAME BODY SYSTEM.

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NUMBER (1) OF SUBJECTS REPORTING ADVERSE EVENTS
BY SEVERITY(1) AND DRUG RELATIONSHIP(2) INCLUDING IDENTIFICATION OF SUBJECTSTREATMENT: Venlafaxine 75 mg (Short)
TOTAL SUBJECTS: 20

BODY SYSTEM (3) ADVERSE EVENT	MILD		MODERATE		SEVERE		TOTAL	
	REL.	NOT REL.	REL.	NOT REL.	REL.	NOT REL.	REL.	NOT REL.
ANY ADVERSE EVENT	4 (20.0)	0	0	0	0	0	4 (20.0)	0
DIGESTIVE SYSTEM	4 (20.0)	0	0	0	0	0	4 (20.0)	0
NAUSEA	4 (20.0)	0	0	0	0	0	4 (20.0)	0
	001-000002							
	001-000007							
	001-000008							
	001-000010							

NOTE: (1)- SEVERITY IS REGARDED AS THE MAXIMUM INTENSITY REPORTED FOR THE ADVERSE EVENTS.
(2)- DRUG RELATIONSHIP IS REGARDED AS THE MAXIMUM DRUG RELATED EVENT FOR THE EVENT SELECTED BY THE SEVERITY
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NUMBER (%) OF SUBJECTS REPORTING ADVERSE EVENTS
BY SEVERITY(1) AND DRUG RELATIONSHIP(2) INCLUDING IDENTIFICATION OF SUBJECTSTREATMENT: Venlafaxine 75 mg (Max)
TOTAL SUBJECTS: 20

BODY SYSTEM (3) ADVERSE EVENT	MILD		MODERATE		SEVERE		TOTAL	
	REL.	NOT REL.	REL.	NOT REL.	REL.	NOT REL.	REL.	NOT REL.
ANY ADVERSE EVENT	3 (15.0)	0	1 (5.0)	0	0	0	4 (20.0)	0
DIGESTIVE SYSTEM	3 (15.0)	0	1 (5.0)	0	0	0	4 (20.0)	0
NAUSEA	3 (15.0)	0	1 (5.0)	0	0	0	4 (20.0)	0
	001-000002		001-000007					
	001-000008							
	001-000009							

NOTE: (1)- SEVERITY IS REGARDED AS THE MAXIMUM INTENSITY REPORTED FOR THE ADVERSE EVENTS.
(2)- DRUG RELATIONSHIP IS REGARDED AS THE MAXIMUM DRUG RELATED EVENT FOR THE EVENT SELECTED BY THE SEVERITY
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NUMBER (%) OF SUBJECTS REPORTING ADVERSE EVENTS
BY SEVERITY(1) AND DRUG RELATIONSHIP(2) INCLUDING IDENTIFICATION OF SUBJECTS

TREATMENT: Venlafaxine 75 mg (XR-Capsule)

TOTAL SUBJECTS: 19

BODY SYSTEM (3) ADVERSE EVENT	MILD		MODERATE		SEVERE		TOTAL	
	REL.	NOT REL.	REL.	NOT REL.	REL.	NOT REL.	REL.	NOT REL.
ANY ADVERSE EVENT	6 (31.6)	0	1 (5.3)	0	0	0	7 (36.8)	0
DIGESTIVE SYSTEM	6 (31.6)	0	1 (5.3)	0	0	0	7 (36.8)	0
NAUSEA	6 (31.6)	0	1 (5.3)	0	0	0	7 (36.8)	0
	001-000009		001-000017					
	001-000012							
	001-000013							
	001-000015							
	001-000019							
	001-000020							

NOTE: (1)- SEVERITY IS REGARDED AS THE MAXIMUM INTENSITY REPORTED FOR THE ADVERSE EVENTS
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